Attachment 2 510(k) Summary

MAR 2 4 2010

a. Regulatory Information

Sponsor/Applicant

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Consultant
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Name of the Device

Trade Name: Extended Use Aldahol High Level Disinfectant
Common Name: Liquid Chemical HLD
Classification Name: Liquid chemical sterilants/high level disinfectants (21 CFR 880.6885)
Classification: Class II

Predicate Name

Aldahol III High-Level Disinfectant (K041360)

Date Prepared

March 19, 2010

b. Device Description

Extended Use Aldahol High Level Disinfectant (HLD) is an aqueous solution that requires the combination of two parts, the unactivated Extended Use Aldahol HLD solution, packaged in gallon-sized containers, and a red Activator Buffer Salt Solution packaged in a smaller container included with the unactivated Extended Use Aldahol HLD solution container.

Once activated, the red/red-orange Extended Use Aldahol HLD as manufactured contains 3.4% w/w of glutaraldehyde and 20.1% w/w of isopropanol in a buffered salt solution of a surfactant, and potassium acetate intended to enhance the antimicrobial activity of the glutaraldehyde

The microbial mode of action of glutaraldehyde has been extensively studied and reviewed since glutaraldehyde was introduced as a disinfectant in the late 1960's. All of these reviews indicate that glutaraldehyde cross-links proteins and lipoproteins of microbes to denature the proteins and lipoproteins, thus killing the cells.

c. Intended Use

Extended Use Aldahol HLD is intended for the high level disinfection or sterilization of clean, heat-sensitive, semi-critical medical devices that are not compatible with other sterilization or high level disinfection processes that can be biologically monitored in Automated Endoscope Reprocessors (AER) where the temperature can be controlled to 25±1°C. Extended Use Aldahol HLD should be used under the following contact conditions:

	Time	Temperature	Minimum Recommended Concentration of Glutaraldehyde
Sterilization	6.0 Hours	25°C	1.8% w/w
High Level Disinfection	5.0 Minutes	25°C	1.8% w/w

Extended Use Aldahol HLD has a reuse period of up to 14 days, or until the glutaraldehyde concentration declines to 1.8% w/w, whichever occurs first. Extended Use Aldahol HLD is intended to be used with 3M Comply 1.8% Glutaraldehyde Monitor Strips Catalog No. 3987 to monitor the glutaraldehyde concentration.

d. Technological Comparison to Predicate

Extended Use Aldahol HLD and the predicate, Aldahol III High-Level Disinfectant, both have the same unactivated and activated formula, and both are glutaraldehyde-based disinfectants combined with isopropanol. The only differences in the two products are the sterilization and disinfection conditions, and the minimum recommended concentration (MRC) of glutaraldehyde. Aldahol III, with an MRC of 2.1% w/w glutaraldehyde is used at 20°C for high level disinfection in 10.0 minutes and sterilization in 10.0 hours. Extended Use Aldahol, with an MRC of 1.8% w/w glutaraldehyde is used at 25°C for high level disinfection in 5.0 minutes and sterilization in 6.0 hours. Both products obtain sterilization and high level disinfection when used per the specific label directions for each product.

e. Non-clinical Efficacy Testing

The following efficacy testing was performed on Extended Use Aldahol HLD with the following conditions: at or below the MRC of 1.8% w/w, aged and stressed to the end of the 14-day reuse period. The testing showed the product to be sporicidal, tuberculocidal, virucidal, fungicidal, and bactericidal.

The bacteria *Staphylococcus aureus*, *Salmonella choleraesuis,* and *Pseudomonas aeruginosa* were killed with exposure for 5.0 minutes at 25°C to Extended Use Aldahol HLD per the AOAC Use-Dilution Test. The fungi *Trichophyton mentagrophytes, Aspergillus niger,* and *Candida albicans* were killed with exposure for 5.0 minutes at 25°C to Extended Use Aldahol HLD per the AOAC Fungicidal Test. Tuberculocidal testing was also performed and >6 $\log_{10}$ of the bacterium *Mycobacterium terrae* were killed within 5.0 minutes at 25°C. The viruses Adenovirus Type 2, Herpes Simplex Virus Type 1, Human Influenza Virus A, and Poliovirus Type 1 were killed within the limits of detection with exposure for 5.0 minutes at 25°C to Extended Use Aldahol HLD in Virucidal Tests. *Bacillus subtilis* and *Clostridium sporogenes* inoculated porcelain penicylinders and silk suture loops were sterilized by Extended Use Aldahol with 6.0 hours of exposure at 25°C per the AOAC Sporicidal Test.

In Simulated Use Tests, the interior channels and exterior surfaces of a bronchoscope, gastroscope, and colonoscope were inoculated with cultures of *M. terrae* and high level disinfected with Extended Use Aldahol with 5.0 minutes exposure at 25°C, killing > 6 $\log_{10}$. In a similar study, a bronchoscope, gastroscope, and colonoscope were inoculated with cultures of *B. subtilis* and sterilized with Extended Use Aldahol with 6.0 hours exposure at 25°C, killing >6 $\log_{10}$. The results of these tests show that Extended Use Aldahol HLD has efficacy as a high level disinfectant and sterilant on actual devices.

f. Clinical Efficacy Testing

Bronchoscopes, gastroscopes and colonoscopes as received directly from patients at an endoscopy clinic, and cleaned, but not disinfected, according to standard cleaning procedures of the clinic, were exposed for 5.0 minutes at 25°C to worst-case Extended Use Aldahol HLD from a 14-day EPA Reuse Test, further diluted to 1.8% w/w glutaraldehyde. No (zero) bacteria were recovered from these endoscopes after the exposure to Extended Use Aldahol HLD.

g. Biocompatibility

Biocompatibility evaluation of product components was conducted. Testing determined that residues of Extended Use Aldahol HLD remaining on endoscopes after sterilization or high-level disinfection and rinsing were well below toxic limits for glutaraldehyde and isopropanol reported in the literature.

h. Material Compatibility

Material compatibility testing demonstrated that Extended Use Aldahol can be used with endoscopes and a variety of materials commonly used in medical facilities at 25°C. With the exception of brass and copper that showed changes after 7 hours, no compatibility issues were found. Extended Use Aldahol is compatible with the materials and devices listed and used according to the Directions for Use.

i. Stability

Extended Use Aldahol (HLD) and the Activator Buffer Salt Solution were tested and both found to be stable at the labeled expiration date.

j. Test Strip

3M Comply 1.8% Glutaraldehyde Monitor Strips Catalog No. 3987 demonstrated the ability to accurately test Extended Use Aldahol HLD at its MRC of 1.8% w/w glutaraldehyde when used according to the Directions for Use.

k. Substantial Equivalence Conclusion

Extended Use Aldahol HLD and the predicate, Aldahol III High-Level Disinfectant, both have exactly the same unactivated and activated formula, and both are glutaraldehyde-based disinfectants combined with 20.1% w/w isopropanol.

Worst case Extended Use Aldahol HLD passed all of the *in vitro* antimicrobial tests with exposures of 5.0 min (or less) at 25° C at 1.8% glutaraldehyde, and passed the simulated use test in bronchoscopes, gastroscopes and colonoscopes within 5.0 min at 25°C at 1.8% glutaraldehyde. Worst case Extended Use Aldahol HLD passed the clinical in-use test in gastroscopes, colonoscopes, and bronchoscopes within 5.0 minutes at 25°C.

Thus Extended Use Aldahol High Level Disinfectant is safe and effective, and substantially equivalent to the predicate, Aldahol III High-Level Disinfectant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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MAR 2 4 2010

Ms. Amy Campbell
Senior Manager, Regulatory Affairs
Healthpoint, Limited
3909 Hulen Street
Fort Worth, Texas 76107

Re: K091890
Trade/Device Name: Extended Use Aldahol High Level Disinfectant
Regulation Number: 21CFR 880.6885
Regulation Name: Liquid Chemical Sterilants/ High Level Disinfectants
Regulatory Class: II
Product Code: MED
Dated: March 19, 2010
Received: March 22, 2010

Dear Ms. Campbell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/ default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Susan Runner

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091890

Device Name: Extended Use Aldahol High Level Disinfectant

Indications for Use:

Extended Use Aldahol High Level Disinfectant is intended for the high level disinfection of reusable, clean, heat-sensitive, semi-critical medical devices which contact intact mucous membranes when the disinfectant is used at or above its minimum recommended concentration of 1.8% glutaraldehyde for 5.0 min at 25°C in an automated endoscope reprocessor with FDA-cleared capability to maintain the exposure of 5.0 min at 25°C.

Extended Use Aldahol High Level Disinfectant is intended for the sterilization of reusable, clean, heat-sensitive critical and semi-critical medical devices which contact and potentially penetrate into sterile body areas, for which there is no other practical method of sterilization, when the disinfectant is used at or above its minimum recommended concentration of 1.8% glutaraldehyde for 6.0 hrs at 25°C.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091890